CLAIMS

1. A therapeutically acceptable glucocorticosteroid which is sterile according to the US Pharmacopoeia 23/NF18.

2. A therapeutically acceptable glucocorticosteroid which is sterile according to the US Pharmacopoeia 23/NF18, with the exception of prednacindone, dexamethasone and prednisolone, and salts, esters and fluoro derivatives thereof.

3. The glucocorticosteroid according to claim 1 or 2 in the form of dry finely divided particles having a mass median diameter (MMD) of less than 10 µm, preferably less than 5 µm.

4.The glucocorticosteroid according to any previous claim having a purity greater than 98.5% by weight, preferably greater than 99.2% by weight.

5. The glucocorticosteroid according to any one of claims 1 to 4, wherein the glucocorticosteroid is selected from the group consisting of glucocorticosteroids with an asymmetric acetal structure comprising 16α,17α-butylidenedioxy, momethasone furoate, beclomethasone dipropionate, and fluticasone propionate, and further esters, acetals and salts thereof.

6. The glucocorticosteroid according to claim 5, wherein the glucocorticosteroid with an asymmetric acetal structure is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

7. A sterile pharmaceutical formulation comprising a therapeutically acceptable glucocorticosteroid which is sterile according to the US Pharmacopoeia 23/NF18 in an aqueous suspension.

8. The sterile pharmaceutical formulation according to claim 7 wherein at least 80% of the glucocorticosteroid particles have a mass median diameter (MMD) of less than 10 µm, preferably at least 60% less than 4 µm.

9. The sterile pharmaceutical formulation according to claim 7 or 8 further comprising one or more pharmaceutically acceptable additives, diluents or carriers.

10. The sterile pharmaceutical formulation according to any one of claims 7 to 9 comprising at least one additive selected from the group consisting of surfactants, pH regulating agents, chelating agents, agents rendering the suspension isotonic and thickening agents.

11. The sterile pharmaceutical formulation according to any one of claims 7 to 10 comprising from about 0.05 to about 20 mg/ml of the glucocorticosteroid, preferably from 0.1 to 5 mg/ml of the glucocorticosteroid.

12. The sterile pharmaceutical formulation according to any one of claims 7 to 11, wherein the glucocorticosteroid is an anti-inflammatory glucocorticosteroid.

13. The sterile pharmaceutical formulation according to any one of claims 7 to 12, wherein the glucocorticosteroid is selected from the group consisting of glucocorticosteroids with an asymmetric acetal structure comprising 16α,17α-butylidenedioxy, momethasone furoate, beclomethasone dipropionate, and fluticasone propionate, and further esters, acetals and salts thereof.

14. The sterile pharmaceutical formulation according to claim 13, wherein the glucocorticosteroid with an asymmetric acetal structure is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

15. A process for the sterilization of a glucocorticosteroid which process comprises heat treating the glucocorticosteroid in the form of a powder at a temperature of from 100 to 130°C.

16. The process according to claim 15, wherein the glucocorticosteroid is an anti-inflammatory glucocorticosteroid.

17. The process according to claim 15 or 16, wherein the glucocorticosteroid is selected from the group consisting of glucocorticosteroids with an asymmetric acetal structure comprising 16α,17α-butylidenedioxy, momethasone furoate, beclomethasone dipropionate, and fluticasone propionate, and further esters, acetals and salts thereof.

18. The process according to claim 17, wherein the glucocorticosteroid with an asymmetric acetal structure is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

19. The process according to any one of claims 15 to 18, wherein the glucocorticosteroid is heat treated at a temperature of from 110 to 120°C.

20. The process according to any one of claims 15 to 19, wherein the glucocorticosteroid is heat treated for no more than 10 hours.

21. The process according to any one of claims 15 to 20, wherein the glucocorticosteroid is heat treated at a temperature of from about 110 to 130°C for no more than 8 hours, preferably no more than 4 hours.

22. The process according to claim 21, wherein the glucocorticosteroid is heat treated at a temperature of about 120°C for no more than 4 hours, preferably no more than 2 hours.

23. The process according to any one of claims 15 to 22, wherein the glucocorticosteroid contains less than about 1 % (w/w) of water, preferably less than 0.5 % (w/w) of water, before the heat treatment.

24. The process according to any one of claims 15 to 23, wherein the glucocorticosteroid powder has a mass median diameter (MMD) of less than 10 µm, preferably less than 5 µm.

25. The process according to any one of claims 15 to 24, characterized in that it is carried out under an inert gas atmosphere.

26. The process according to any one of claims 15 to 25, characterized in that the amount of heat resistant spores is reduced by more than log 6, preferably by more than log 7.

27. The process according to any one of claims 15 to 26, characterized in that the D value is less than about 240 min, preferably less than 90 min, at the preselected temperature T, wherein T is in the range of from 100 to 130°C.

28. Use of a glucocorticosteroid according to any one of claims 1 to 6 or a formulation according to any one of claims 7 to 14 in the manufacture of a medicament for use in the treatment of an allergic condition and/or inflammatory condition of the nose or lungs.

29. Use of a glucocorticosteroid or a formulation according to claim 28 in the manufacture of a medicament for use in the treatment of chronic obstructive pulmonary disease (COPD), rhinitis or asthma.

30. Method for treatment of an allergic and/or inflammatory condition of the nose or lungs comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a glucocorticosteroid according to any one of claims 1 to 6 or a formulation according to any one of claims 7 to 14.

31. Method for treatment of chronic obstructive pulmonary disease (COPD), rhinitis or asthma comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a glucocorticosteroid or a formulation according to claim 30.